

**The Growth and Institutionalization of Narcotic Conservatism:**

**The Historical Background of the U.S. Opioid Addiction and Overdose Crises**

Expert Report and Appendices Pertinent to the Opioid MDL

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## Credentials and Biographical Sketch

David T. Courtwright is Presidential Professor in the Department of History of the University of North Florida. He has taught at the university for thirty years and in April 2019 he will assume the status of presidential professor emeritus. He is an internationally recognized authority on the history of drug use and drug policy, a research area in which he has published since 1978.

Courtwright's books include *Dark Paradise: A History of Opiate Addiction in America* (Harvard University Press, 1982, revised 2001); *Addicts Who Survived: An Oral History of Narcotic Use in America before 1965* (University of Tennessee Press, 1989, revised 2012); *Forces of Habit: Drugs and the Making of the Modern World* (Harvard University Press, 2001); and *The Age of Addiction: How Bad Habits Became Big Business* (Belknap Press of Harvard University Press, May 2019). Two other books, *Violent Land: Single Men and Social Disorder from the Frontier to the Inner City* (Harvard University Press, 1996) and *No Right Turn: Conservative Politics in a Liberal America* (Harvard University Press, 2010) describe drug use and drug policy in relation to U.S. social and political history.

Courtwright's drug-related articles have appeared in the *New England Journal of Medicine*, *Annual Review of Public Health*, *Addiction*, *BioSocieties*, *Social History of Alcohol and Drugs*, *Business History*, *Drug and Alcohol Dependence*, and other journals listed in the appended c.v.

Courtwright has received several awards for his scholarly work. These include an appointment as the 2015 Douglas Southall Freeman Professor of History at the University of

Richmond and a research fellowship from the American Council of Learned Societies. He has received fellowships from the National Endowment for the Humanities, which in 2015 named him an inaugural recipient of its highly competitive Public Scholar Award. In 2002 the College of Problems on Drug Dependence conferred its Media Award for *Forces of Habit*, which also received the journal *Addiction*'s annual book award. With translations into Chinese, Japanese, French, Spanish, and Swedish, *Forces of Habit* has become both a standard international history of drug use and a widely read introduction to the field.

Courtwright has served as a member of the Institute of Medicine's Substance Abuse Coverage Committee, which in 1990 reported to Congress on the adequacy of U.S. drug abuse treatment. From 2009 to 2011 he served as president of the Alcohol and Drugs History Society (ADHS), an international scholarly organization dedicated to the study of licit and illicit drugs. He continues to serve on the ADHS's executive board and on the editorial board of its journal, *The Social History of Alcohol and Drugs*, published by the University of Chicago Press.

Courtwright has twice served as a primary grant reviewer for the National Institute on Drug Abuse. He has refereed articles for medical journals, including the *New England Journal of Medicine* and the *American Journal of Public Health*, and history journals such as the *Bulletin of the History of Medicine*, on whose editorial board he also sits. He has refereed drug-history related book proposals and manuscripts for California, Cambridge, Chicago, Harvard, Johns Hopkins, North Carolina, NYU, Oxford, and other university presses.

Journalists in print and electronic media have interviewed Courtwright extensively. He has been quoted in such publications as the *New York Times*, the *Washington Post*, the *Atlantic*, *Smithsonian Magazine*, *CQ Researcher*, *Vox*, and the *Huffington Post*. His work has been

featured in such programs as National Public Radio's "All Things Considered" and "Weekend Edition;" Radio France's "La Fabrique de l'histoire" and "Culturesmonde;" the Australian Broadcasting Company's "Rear Vision;" and Virginia Public Radio's "Back Story." He has been invited to give lectures and papers on drug-history related topics in such venues as the Yale School of Medicine; Harvard's Kennedy School of Government and Radcliffe Institute for Advanced Study; the London School of Economics; Cambridge University; the National History Center; and the Office of National Drug Control Policy.

Courtwright has been recognized as an expert witness in federal district courts in Florida, Georgia, and Missouri. In 1993 and 1994 he testified about the historical background of U.S. drug laws in relation to constitutional challenges to crack-cocaine sentencing provisions. He has not testified as an expert witness since 1994. He has been retained to testify as an expert witness in the history of opioid crises in the United States by the Attorney General of Oklahoma.

Courtwright is being compensated at a rate of \$450 an hour for his services.

### **Note on Historical Methods**

Historians use a variety of methods to pursue a common goal, reconstructing a true story about the past. Different topics require different methods. The most appropriate methods for a history of U.S. narcotic addiction epidemics in relation to changing therapeutic norms are the standard quantitative and qualitative techniques employed by historians of medicine. These include 1) the statistical analysis of data from such sources as collections of case histories, surveys of physicians and pharmacists, records of drug imports, and prescription samples; 2) the assembly and review of hearings, reports, statutes, regulations, and correspondence from

government entities charged with regulating medical practice and controlling drug use; 3) the recording, transcription, and analysis of oral history interviews with a range of subjects, from patients in treatment to medical opinion leaders; and 4) the location and close reading of pertinent primary and secondary sources. Examples of primary sources consulted in this report include archived letters, minutes, and reports; advertising and promotional materials; articles published in contemporaneous medical journals and newspapers; and contemporaneous medical monographs and textbooks. Examples of secondary sources are books, articles, and conference papers written by professional historians; similar works by credentialed scholars in other social-science disciplines; and published accounts by investigative reporters with access to primary sources. These are all types of sources that medical historians rely upon professionally.

A key question in medical-historical investigations is whether the quantitative and qualitative analyses converge in support of a hypothesis. If, for example, one posits that addiction prevalence was rising (or falling) during a certain period, one ascertains whether the statistical evidence, contemporary observations, official reports, interviewee recollections, and secondary accounts consistently support the hypothesis. If not, one must account for the anomalous findings, for example by reference to known regional variations in addiction prevalence.

Once medical historians have identified patterns and explained (also on the basis of interlocking quantitative and qualitative analyses) why these patterns changed over time, they submit their work for peer review and criticism. Reviewers call attention to potentially contradictory evidence, possible alternative explanations, unexplored data sources, and other issues that must be addressed before publication.

Here I would add that the core historical finding of this report—that liberal prescribing practices have fostered iatrogenic opioid addiction, while conservative prescribing practices have prevented it—has been subjected to peer review and has already appeared in print. I have made this and other arguments in refereed books and articles published by selective university presses and journals that require review by multiple peers whose identities are unknown to the authors. The secondary historical sources on which I draw, such as books and articles by Professors Caroline Acker and David Musto, have undergone similar independent review processes. They too appeared in print years before the 2018 filing of the second amended complaint for the opioid MDL, the document I received when I agreed to serve as an expert consultant.

## **Opinions**

In the course of an epidemic of opiate addiction in the late nineteenth century medical and pharmaceutical professionals learned that it was dangerous to prescribe narcotic drugs to patients suffering from what is now called chronic nonmalignant pain (CNP). The principal risk of such treatment was addiction.

The knowledge of the addictive danger of prescribing narcotics for CNP was significant, lasting, and institutionalized.

It was significant because it helped end, through primary prevention, the country's first major opiate addiction epidemic.

It was lasting because warnings against prescribing narcotics for CNP became a fixture of medical instruction and literature.

It was institutionalized because it was expressed in laws and regulations enforced by federal agencies that oversaw the licit narcotics trade. Regulators warned pharmaceutical manufacturers and distributors of the addictive potential of new semi-synthetic and synthetic products that they proposed to market.

This cautionary knowledge and these institutions prevented further large-scale epidemics of iatrogenic narcotic addiction until the end of the twentieth century. While there were periodic increases in *heroin* addiction, notably from the late 1940s to the early 1950s, and again from the late 1960s to the early 1970s, these episodes were nonmedical in character.

The precondition for the restoration of a mass market for prescription narcotics and, consequently, for a second large-scale epidemic of medical narcotic addiction was that cautionary axioms about treating CNP with opioids had to be inappropriately revised or rendered irrelevant. Prescription narcotic gatekeepers, medical and institutional, had to be persuaded that the warnings about iatrogenic addiction and related risks had been overemphasized to the detriment of pain patients. That, or the warnings no longer applied to newer narcotic remedies that were safe and non-habit-forming.

### **Introduction: Opiate Addiction Epidemics in American History**

Prior to the current epidemic of *opioid* addiction, the United States experienced three historically significant epidemics of *opiate* addiction. They were epidemics in the sense that each

entailed an unexpectedly rapid increase in the number of new cases. They were opiate addiction epidemics because “opiate” was the adjective contemporaries then used for opium-based drugs.<sup>1</sup>

The first of the three opiate addiction epidemics involved opium and morphine. It began around 1870 and peaked in the mid-1890s. A second, which involved heroin, occurred in the late 1940s and early 1950s. A third and larger heroin epidemic occurred in the late 1960s and early 1970s. The number of U.S. addicts ballooned to around 600,000, an increase reflected in the diagram attached as Appendix B.

Neither of the twentieth-century heroin epidemics originated in medical practice. After 1924 heroin was essentially an outlaw drug, an arrangement formalized by the 1970 Controlled Substances Act (CSA). However, the first opiate addiction epidemic, in the late nineteenth century, was different in character. Like the current opioid addiction epidemic, it had two main sources of initiation, medical and nonmedical usage.

The primary nonmedical source of the nineteenth-century epidemic was opium smoking by Chinese immigrants. This practice, widely regarded as a vice, spread in the white underworld during the 1870s and 1880s. The primary medical source of the first epidemic was the diffusion of hypodermic medication among American physicians that likewise occurred during the 1870s and 1880s. Patients also became addicted through self-medication with patent medicines or

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<sup>1</sup> As late as 1974 *Dorland's Illustrated Medical Dictionary*, a standard authority, contained no entry for “opioid.” It made reference only to “opiate,” defined as “a remedy containing or derived from opium.” *Dorland's Illustrated Medical Dictionary*, 25<sup>th</sup> ed. (Philadelphia: W.B. Saunders, 1974), 1092. “Opioid” did come into common usage until the late 1970s and 1980s.

laudanum or other narcotic remedies. But the most common cause of medical addiction was the hypodermic administration of morphine, typically initiated by a physician. The likelihood of addiction increased if the physician or patient continued the injections during the course of an extended and painful illness. Hundreds of reports of iatrogenic (physician-initiated) morphine addicts appeared in late nineteenth-century medical journals.

Two cases, both reported in 1890, serve to illustrate the situation. The first was of a sixteen-year-old Vermont girl suffering pelvic cellulitis. In 1882 a homeopathic physician began relieving her pain with 1/8 grain (8 mg) of morphine hypodermically. A regular practitioner who later (and critically) described the case wrote that, “to save himself the annoyance of being called upon so often,” the girl’s doctor told her to procure a hypodermic syringe and use 1/4 grain (16 mg) at a dose. “This she did, and now with the reins in her own hands she steadily increased the dose and its frequency.” By 1890, when the patient died at age twenty-four, she was injecting 20 grains (nearly 1,300 mg) daily.<sup>2</sup>

The original reason that the girl’s physician injected morphine was to provide prompt relief from the pain caused by a stubborn bacterial infection about which he could otherwise do nothing. Late-nineteenth-century physicians often remarked patients’ suffering. They knew that, when it came to alleviating painful symptoms, an injection of morphine had no equal. Adding to the addiction risk, no law prevented the woman from heeding her doctor’s advice of procuring her own hypodermic syringe and continuing the injections indefinitely. State control of

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<sup>2</sup> E. W. Shipman, “The Promiscuous Use of Opium in Vermont,” *Transactions of the Vermont Medical Society*, no vol. (1890), 74-75.

medicinal opiate sales was then weak or nonexistent. Virtually all drug stores stocked opiates. Wholesalers like McKesson and Robbins kept local druggists supplied with a variety of injection equipment.<sup>3</sup>

Doctor-addicts had their own hypodermic syringes. The second representative case was that of a physician who began treating his facial neuralgia with “small doses” of morphine around 1877. Ten years later he had worked himself up to 30 grains (1994 mg) of morphine daily. His bloated body was covered with hypodermic abscesses that ran from his shoulders to his calves. He died in 1887, age 40. Apart from the initial self-administration, the pattern was largely the same as the first case: Ongoing, often intense pain, followed by relief with morphine injections, followed by dependence, tolerance, escalating doses, and addiction, followed by complications and early death.<sup>4</sup>

Such deaths were preventable, as a generation of concerned physicians, legislators, journalists, and regulators came to understand. America’s first encounter with widespread opiate addiction, in the late nineteenth century, taught a vital lesson. The lesson was that it was unwise to use narcotics, above all potent narcotics like morphine, to treat chronic pain, always excepting pain from terminal disease.

The first section of this report shows how this lesson was learned from 1870 to 1919; the second how it was reinforced by educational, legal, and regulatory practice through most of the

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<sup>3</sup> McKesson and Robbins, *Illustrated Catalogue of Druggists’ Sundries, Fancy Goods, Surgical Instruments, Sponges, Chamois, etc.* (New York: Daniel G. F. Class, 1883), 137.

<sup>4</sup> Shipman, “Promiscuous Use of Opium in Vermont,” 74.

twentieth century. Each section examines a drug or drugs (prescription heroin, methadone and oxycodone) to illustrate shifts in attitudes and practices. Excerpts from primary sources show how thinking evolved with respect to the perennial problem of prescribing and regulating narcotic medications.

## I. The Growth of Narcotic Conservatism

### A. Lessons Learned: Doctors, Pharmacists, Opiates, and Pain, 1870-1919

Opium addiction was comparatively rare in the United States prior to 1830, morphine addiction rarer still. The medical literature on opiates focused, not on addiction, but on indications, contraindications, and toxic effects, which physicians confronted in cases of deliberate or accidental overdose. Opium was not infrequently deployed as a home remedy, particularly for diarrheal complaints. It was given to children as well as adults. When dosages were misjudged, misfortunes followed.<sup>5</sup>

Statistical and literary evidence suggests that opiate addiction became somewhat more widespread during the mid-nineteenth century, years punctuated by outbreaks of cholera and dysentery. The problem did not, however, become a full-blown epidemic until the 1870s and 1880s, decades during which the nation's per capita consumption of opiates approximately tripled. The lingering physical and psychological trauma of the Civil War was one factor, though

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<sup>5</sup> The early nineteenth-century concern with opium toxicity is apparent in Hugo Krueger et al., *The Pharmacology of the Opium Alkaloids*, part 2, supplement no. 165 to the *Public Health Reports* (Washington, D.C.: Government Printing Office, 1943), 1089-93.

not the primary one. Survey data consistently showed that white, native-born women made up the majority of medicinal opium and morphine addicts, and that medical personnel were far more frequently addicted than veterans. The two most important risk factors were exposure to narcotics and a history of chronic illness. Regardless of the addict's sex, palliation of recurrent pain and distress from such conditions as neuralgia, migraine, neuroma, chronic respiratory or gastrointestinal infection, anxiety, depression, and dysmenorrhea (painful menstruation) was the most common origin of addiction. "Uterine and ovarian complications," New York physician Frederick Heman Hubbard wrote in 1881, "cause more ladies to fall into the habit, than all other diseases combined." Opium smoking to one side, late-nineteenth-century addiction was fundamentally a byproduct of medicating or self-medicating painful disorders.<sup>6</sup>

Hubbard, like other addiction specialists in the 1880s, grasped that subcutaneous injection was the most dangerous and seductive method of administration. Patients, he wrote, became familiar with the technique, acquired their own syringe, and were soon "confirmed in the habit." Specialists throughout Europe and the United States seconded his warning. Symptomatic

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<sup>6</sup> David T. Courtwright, *Dark Paradise: A History of Opiate Addiction in America*, rev. ed. (Cambridge, Mass.: Harvard University Press, 2001), chap. 2. The quotation is from Fred. [sic] Heman Hubbard, *The Opium Habit and Alcoholism* (New York: A.S. Barnes & Co., 1881), 17.

treatment with opiates, which inherently risked addiction and other complications, was riskier still when relief came in the form of morphine injection.<sup>7</sup>

Hypodermic medication gained a foothold in America in 1856, though it was not until well after the Civil War that most rank-and-file practitioners embraced the new technology. At first they were enthusiastic. “I now enter the chamber of *suffering*,” Georgia physician Dr. William Greene wrote in 1867, “*knowing* that I have in my possession an *unfailing* remedy for pain. ‘Relieve me of my pain, Doctor,’ is the cry of the sufferer. With a Hypodermic syringe, this agonizing cry can be promptly, and without injury, hushed.”<sup>8</sup>

By 1870, however, medical journal contributors and correspondents were calling attention to the addiction risk of hypodermic administration. When New York City physician J.G. Sewall read a report that “when the long-continued use of morphia is required, the danger of the habit of opium eating will be avoided if we inject the opiate,” he objected. The opinion was “entirely a mistaken one,” he wrote, “and calculated to lead to grave errors in practice.” Sewall offered two cases, including that of a forty-year-old neuralgia sufferer who had become addicted, badly confused, and covered with puncture marks. That same year, 1870, warnings of the dangers of iatrogenic morphine addiction appeared in English-language journals published as far

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<sup>7</sup> Hubbard, *Opium Habit*, 162. H. H. Kane, *Drugs that Enslave: The Opium, Morphine, Chloral and Hashisch Habits* (Philadelphia: Presley Blakiston, 1881), chaps. 2, 7, summarizes international opinion and reiterates the dangers of hypodermic administration.

<sup>8</sup> William A. Greene, “Hypodermic Administration of Medical Agents,” *Atlanta Medical and Surgical Journal* 8 (1867): 97, all italicization and capitalization thus.

apart as California and Great Britain. “Most impatiently did she await the injection, morning and evening, often crying like a child,” an alarmed physician wrote of a neuralgic woman under his care. “And always exclaiming, as I entered—“Oh doctor, shoot me quick!””<sup>9</sup>

These 1870 reports mark the beginning of the modern debate over the use of novel, potent, technologically advanced narcotic remedies that were purportedly safe and effective for treating chronic, nonterminal pain. Three points should be noted. First, the debate commenced well over a century before the introduction of another generation of purportedly safe narcotics like OxyContin or Opana ER. Second, the debate drew attention to the danger, not only of addiction, but to addiction’s physical and psychological sequelae: infections, overdoses, opiate-dependent newborns, and declining self-control and moral character. Third, the debate was resolved in favor of the skeptical position. Increasing numbers of physicians and journalists weighed in on the dangers of iatrogenic opiate addiction. The frequency and sophistication of their admonitory articles and published medical-journal correspondence increased throughout the 1870s and 1880s, even as the opiate addiction epidemic worsened.

Representative of these dressing-downs was Dr. James F.A. Adams’s “Substitutes for Opium in Chronic Disease,” which appeared in 1889 in the *Boston Medical and Surgical*

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<sup>9</sup> J. G. Sewall, “Opium-Eating and Hypodermic Injection,” *Medical Record* 5 (1870): 137; H. Gibbons, “Letheomania: The Result of the Hypodermic Injection of Morphia,” *Pacific Medical Journal* 12 (1870): 481, 495, “quick” p. 487 (quotation also appears on p. 7 of the offprint of the Gibbons article published by F. Clarke [San Francisco, 1870]); Clifford Albutt, “On the Abuse of Hypodermic Injections of Morphia,” *Practitioner* 5 (1870): 327-331.

*Journal.* Dr. Adams reminded colleagues of three basic truths. First, opiates were highly toxic. Second, their benefits were offset by side effects that ranged from constipation to depression. Third, opiate therapy often led to addiction. Dr. Adams judged that 150,000 Americans had fallen victim to the “opium-habit” (a nineteenth-century term for addiction to any type of opiate), not counting those who had brought it on themselves by smoking the drug. Why not, Dr. Adams urged, use newer, non-opiate analgesics and hypnotics to treat the symptoms that commonly motivated patients to seek out physicians?<sup>10</sup>

Dr. Adams’s advice was sound. Yet it also raises a question. Why, if doctors were warned for nearly twenty years about the risk of iatrogenic addiction, did per capita consumption of medicinal opiates keep climbing, not reaching a peak until about 1895?

The answer is that the American medical profession was in a sorry state from 1870-1895. Scientific medicine was in its infancy. The average practitioner was poorly educated, possessing no more than two years of instruction in a proprietary medical school. Doctors lacked effective treatments for most diseases. The heart of medical practice remained diagnosis, prognosis, case management, and symptomatic treatment. Opiates were enormously tempting in this last regard, being potent pain relievers in the short term. Opiates developed a reputation as the “the lazy physician’s remedy,” a convenient way to pacify a pain patient without exerting effort to investigate the underlying disorder. Even physicians who were neither incompetent nor indolent faced economic pressure to prescribe. In the late nineteenth century too many doctors competed

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<sup>10</sup> J.F.A. Adams, “Substitutes for Opium in Chronic Disease,” *Boston Medical and Surgical Journal* 121 (1889): 351-56.

for too few discretionary dollars from too few patients. Professional incomes averaged around \$1,000 a year, or \$28,000 in 2018 dollars. Doctors faced stiff competition from sectarian practitioners, as well as from colleagues with regular medical training. Physicians knew that, if they did not “shoot first,” a rival might, thereby gaining a valuable patient.<sup>11</sup>

Then, from 1895 to 1915, the first narcotic addiction crisis waned. It did so for several interrelated reasons, all tied to medical progress. Surgery, revolutionized by antiseptic and aseptic techniques, affected lasting cures for some painful conditions. Public health reform, rationalized by advances in bacteriology, reduced infectious disease morbidity and mortality, particularly in cities. The prevalence of diarrheal diseases, often treated with opiates, declined. Greater diagnostic precision, made possible by new technologies like X-rays or Wassermann tests for syphilis, discouraged the unthinking palliation of disease. Should symptomatic treatment still be required, new, non-opiate alternatives for pain and fever were emerging: acetanilide, phenacetin, and, ultimately, aspirin, which was introduced commercially in 1899 and soon became Bayer Pharmaceutical’s best-selling product. Though these drugs were not without side

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<sup>11</sup> T.D. Crothers, “Medicolegal Relations of Opium Inebriety and the Necessity for Legal Recognition,” *Journal of the American Medical Association*, hereafter *JAMA*, 35 (1900): 413, “lazy” (comment on Dr. Crothers’s paper by Dr. Kenniston); Paul Starr, *The Social Transformation of American Medicine* (New York: Basic Books, 1982), chaps. 1-2, income statistics pp. 84-85; Courtwright, *Dark Paradise*, 50-51.

effects, recommending them for painful conditions like headache or arthritis was safer than prescribing opiates.<sup>12</sup>

There remained the problem of self-medication. Many patent medicines (proprietary, heavily advertised nostrums based on secret formulae) contained opiates. Many pharmacists honored ancient, tattered prescriptions or simply dispensed with formalities and sold narcotics directly to addicts. Morphine and soda water, admitted one, kept him in business. Even reputable druggists made their excuses, saying that to refuse sale would simply alienate customers, who would go elsewhere to purchase their drugs.<sup>13</sup>

Progressive doctors and pharmacists therefore lobbied, with growing success, for laws to regulate narcotic sales. One key piece of federal legislation was the 1906 Pure Food and Drug Act, which required patent medicine makers to list their ingredients. Wary consumers, whose worries were reinforced by muckraking journalists, looked at the list of toxic drugs on the label and decided they wanted no part of the product. Sales of all patent medicines containing opiates were down, a Boston wholesale druggist reported in 1908. The “trade in Winslow’s Soothing

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<sup>12</sup> Courtwright, *Dark Paradise*, 51-52; Jan R. McTavish, “Aspirin in Germany: The Pharmaceutical Industry and the Pharmaceutical Profession,” *Pharmacy in History* 29 (1987): 103-115.

<sup>13</sup> “The Opium Habit’s Power,” *New York Times*, December 30, 1877, p. 8.

Syrup has been almost wiped out.” Druggists who had once ordered bottles “by the carload” now handled only “a few dozen at a time.”<sup>14</sup>

Even more basic to reform was the effort to enact and enforce local and state laws limiting narcotic sales to patients with a valid prescription from a licensed physician. By 1915 almost every state had enacted such a law. Ohio, for example, required the original, written prescription of a state-licensed physician, dentist, or veterinary surgeon for the legal purchase of narcotics. The two exceptions under Ohio law were “liquid preparations sold in good faith as medicines” that contained only small amounts of opiates or sales by wholesalers to “duly registered” pharmacists, physicians, dentists, and veterinary surgeons. The State further required pharmacists to keep prescriptions on file for at least two years and to dispense morphine in vials containing no more than one dram (1772 mg) of the drug. Possession by unauthorized Ohioans without a prescription was “prima-facie evidence of violation of the law” and could result in fines, imprisonment, or both. Newspaper reports—the tip of the prosecutorial iceberg—show that

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<sup>14</sup> John Phillips Street, “The Patent Medicine Situation,” *American Journal of Public Health* 7 (1917): 1037-38; William P. Millay to Hamilton Wright, August 24, 1908, box 29, and “Boston Notes” (TS, 1908), no pp., quoting Mr. Carter of Carter, Carter, & Meigs, box 43, both Records of the United States Delegation to the International Organization and Conference (hereafter USIOC), Record Group 43, National Archives, Washington, D.C. Sales likewise fell in Maine and Vermont, in part because these states also restricted sales of narcotic nostrums. The best-known journalistic exposé of the patent-medicine industry was Samuel Hopkins Adams, *The Great American Fraud*, 4<sup>th</sup> ed. (Chicago: Press of the American Medical Association, 1907).

Ohio brought at least 41 cases for illegal sale and possession in 1914, making it one of the most active anti-narcotic-abuse states in the nation.<sup>15</sup>

Pharmacists and suppliers who dodged the new laws faced the threat of professional ostracism as well as prosecution. “Dope” doctors and “unscrupulous” pharmacists were roundly condemned. One New York pharmacist wrote that every drug store should post a sign, “A greedy criminal druggist will sell you morphine or cocaine; we are not of that kind.” Charles A. West, another prominent Boston wholesale druggist, said that when his firm received orders for opiates from those not entitled to them he refused to fill them and returned their money. By the early twentieth century ethical pharmacists steered clear of black or gray markets.<sup>16</sup>

One such pharmacist, Henry P. Hynson, gave a candid appraisal of the situation. Hynson was a manufacturing pharmacist in Baltimore, a professor of commercial pharmacy at the

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<sup>15</sup> M.I. Wilbert, “Efforts to Curb the Use of Narcotic Drugs,” *Public Health Reports* 30 (1915): 893-923, Ohio laws and data on pp. 895, 897, 916-917, quotations on pp. 916 and 917. Ohio law defined small amounts in exempt preparations as no more than 2 grains of opium or one-quarter grain of morphine or heroin. It also forbade operating or visiting opium dens, another common feature of state and municipal statutes.

<sup>16</sup> “Portland, Maine, Notes” (TS, 1908), no pp., box 43, USIOC (“unscrupulous”); “We Want to Know,” *Pharmaceutical Era* 29 (1903): 445 (“greedy”); Charles A. West to Hamilton Wright, August 14, 1908, vol. 3, Massachusetts to New Mexico correspondence, USIOC.

University of Maryland, and an influential member of the American Pharmaceutical Association. These are the notes of an interviewer who spoke to him in 1908:

Hynson ... stated that the American Pharmaceutical Association strongly approves of the anti-opium crusade and has done a great deal in the last few years to direct the sale of narcotic drugs to licit channels and necessary use. He says that a few unscrupulous drug jobbing houses in Baltimore sell opium, morphine and other opium derivatives at retail to old habitués. First-class manufacturing chemists sell only to jobbers and first-class jobbers only to retail druggists. This is the general practice throughout the country.

A large number of retail druggists are unscrupulous and will sell opium and its derivatives whenever they can. Quantities of morphine are sometimes brought in from other cities and sold from hand to hand on the Baltimore streets. This has, however, been largely stopped since a new local ordinance passed, making it both finable and imprisonable not only to use or sell but to be found in possession of narcotics.

He knows personally of about 50 cases of the habitual hypodermic use of morphine, the habit having been contracted as the result of careless prescribing. He does not sell proprietary medicines containing opium, etc. He thought there had been a 25 % reduction in the sale of such medicines since the Pure Food and Drug Act went into effect.

In his business today he prescribes [sic] less morphine than five years ago, because of the tendency on the part of physicians and surgeons to operate on those cases that formerly had opium in some form prescribed to lessen pain, or to the use of coal tar anodynes. He thought that the present practice of operating for painful diseases has appreciably

lessened the amount of morphine used legitimately in this country and that, on the whole, there should have been a decrease rather than an increase in our importations of opium and morphine.<sup>17</sup>

In fact, there had been a steady decrease in the per capita consumption of medicinal opiates during the first decade of the twentieth century. Though some officials had suggested otherwise, in hopes of spurring further diplomatic and legislative action, per capita imports were trending down, as were the percentages of prescriptions containing opiates. In 1888, 14.5 percent of prescriptions filled in Boston drug stores contained opiates. In 1908, the comparable figure for California was 3.6 percent.<sup>18</sup>

The question of who was writing frequent narcotic prescriptions also drew the attention of researchers. In 1919 Dr. Thomas S. Blair, head of the Pennsylvania Bureau of Drug Control, reported that one-third of state's physicians and dentists wrote 90 percent of narcotic prescriptions. While perhaps 150 of these men were out-and-out "dope doctors," mostly addicts themselves, the heavy prescribers were more typically older and less competent practitioners

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<sup>17</sup> "Professor Henry P. Hynson," *Drug Trade Weekly* 4 (April 23, 1921), 15; "Baltimore Notes" (TS, 1908), box 43, USIOC, with minor spelling corrections and paragraph breaks.

<sup>18</sup> Virgil G. Eaton, "How the Opium Habit is Acquired," *Popular Science Monthly* 33 (1888): 665 (Boston); Charles B. Whilden, California State Board of Pharmacy, to Hamilton Wright, September 17, 1908, p. 4, box 43, USIOC. For per capita trends and additional USIOC correspondence corroborating the decline in medicinal opiate consumption see Courtwright, *Dark Paradise*, pp. 25 (figure 5) and 213-214 n 139.

who had been trained before the dangers of opiates were stressed. By contrast, the conservative prescribers (8,000 of the state's 12,000 doctors) were either younger and better trained or in mid-career and "keeping abreast of the times." Dr. Blair's description of their outlook defines narcotic conservatism and shows how doctors' attitudes shifted during the early twentieth century, when a rising generation equated caution in prescribing opiates with medical progress and ethical practice:

These physicians are seeking for remedies specifically meeting definitely diagnosed pathology, whether the remedy be a drug, a serum, a vaccine or surgical intervention. But they know that specific remedies are few, and, so, they stress case-management in the run of practice, regarding the administration of symptomatic medication as only a *part* of case-management, and, often, the least important part. They know from experience and from reading that the narcotics *cure* no condition having a definite pathology, and they regard the administration of narcotics as emergency symptomatic medication, to meet violent pain and spasm, certain surgical and traumatic emergencies, acute inflammation of serous membranes, aggravated dyspnea, cases of pneumonia and typhoid fever with talkative delirium in which the patient simply *must* have sleep, inoperable cancer, and so on. They know that, in certain aggravated conditions, the temporary use of a narcotic is lifesaving, even though it is not specifically curative; and, thus, they prescribe narcotics conservatively and scientifically, ever keeping in view the associated danger of addiction. No law interferes with such practice, and these physicians no more think of supplying to a patient at one time 200 morphine pills than they do of giving an equal number of calomel tablets or aconitine granules.

Calomel was a violent, mercury-based purgative associated with the bygone days of depletion-based therapeutics. Aconitine was a notoriously toxic alkaloid sometimes administered in small doses to treat pain and other symptoms. By analogy and implication, unthinking palliation with frequent and heavy doses of narcotics was a risky and retrograde medical practice, associated with doddering “routinists” or venal doctors out for a quick buck.<sup>19</sup>

### **B. Illustration: The Scarcity of Iatrogenic Heroin Addiction, 1898-1924**

Because physicians were becoming gatekeepers for licit narcotic commerce—no valid prescription, no legal sale—the growth of narcotic conservatism helped both to prevent medical addiction and reduce its prevalence. The clearest example of this trend was heroin, a semisynthetic prescription opiate introduced in 1898. Though heroin was similar to oxycodone in its molecular structure and narcotic effects, it had a dissimilar early history, owing to a combination of more narrowly focused marketing and more skeptical evaluation. For all its potency, heroin triggered no wave of iatrogenic addiction remotely comparable to that which followed the popularization of morphine injections or the introduction of oxycodone pills for treating CNP.

Medically induced heroin addiction was in fact rare. In 1918 Dr. Carl Scheffel, an expert on medical jurisprudence, described the background of fifty addicted patients who had voluntarily sought cures. Addiction treatment being expensive, his sample consisted largely of

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<sup>19</sup> Thomas S. Blair, “Is Opium the ‘Sheet-Anchor of Treatment’?” *American Journal of Clinical Medicine* 26 (1919): 830-831, italics in original, and “The Dope Doctor and Other City Cousins of the Moonshiner,” *Survey* 44 (1920), 18 (routinists).

middle-class medical addicts. Only one of the patients, a victim of trigeminal neuralgia, had become addicted by using heroin. The rest followed the traditional pattern, most having become addicted after a physician prescribed morphine for a chronic and painful condition.<sup>20</sup>

Psychiatrist Lawrence Kolb, who became the federal government's leading authority on narcotic addiction in the 1920s and 1930s, reached the same conclusion. With Dr. John Remig, a Pennsylvania State Health Department drug-control inspector, Kolb reviewed the cases of 150 medical addicts who had begun using narcotics between 1898 and 1924—that is, between the year Bayer introduced heroin and the year Congress outlawed its manufacture. They found just two heroin users, 1.3 percent of the total. Kolb's hypothesis, "the use of heroin in medical practice seldom resulted in addiction," was borne out. Heroin addiction overwhelmingly originated from use "in the underworld for dissipation."<sup>21</sup>

Why were there so few medical heroin addicts? First, Bayer's marketing was relatively restrained. In contrast to morphine and cocaine, which had been introduced earlier and touted for a wide range of conditions, the literature on heroin emphasized its role as a specific in treating cough and respiratory disorders. It was often administered in small doses (some as low as 1 or 2 mg) and in tablet, pastille, or syrup form rather than by injection. "The fact that the therapeutic

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<sup>20</sup> Carl Scheffel, "The Etiology of Fifty Cases of Drug Addictions," *Medical Record* 94 (1918): 853-854.

<sup>21</sup> "Questionnaire [sic] re Drug Habit," box 6, and Kolb to Remig, November 14, 1927, box 4, both Lawrence Kolb Papers, History of Medicine Division, National Library of Medicine, Bethesda, Maryland.

dose of heroin was much smaller than that of morphine made it less likely for heroin to cause addiction when it was prescribed,” Kolb observed. A 1906 *Journal of the American Medical Association (JAMA)* literature review noted that heroin was “recommended chiefly for the treatment of the air passages attended with cough, difficult breathing and spasm”—in other words, conditions like bronchitis, pneumonia, tuberculosis, or asthma. The same review nonetheless cautioned that heroin depressed respiration, that it was toxic in higher doses, and that addiction formed readily and with deplorable consequences. A few authorities did venture, in print, that heroin would make an effective general analgesic. This idea, however, was controversial. It soon drew fire from both German and American physicians.<sup>22</sup>

Medical writers also rebutted a handful of early reports that heroin was not addictive and that it might serve as a treatment for morphine addiction. In a short-term sense this was true. Heroin, which breaks down into morphine and codeine in the bloodstream, bought temporary relief from opiate-addiction withdrawal symptoms. But that was hardly a cure. On close inspection, heroin looked every bit as dangerous as its predecessor alkaloids.

In a 1903 article, “The Heroin Habit Another Curse,” Dr. George F. Pettey, a Memphis, Tennessee, addiction specialist, stated the case for wariness:

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<sup>22</sup> Lawrence Kolb, *Drug Addiction: A Medical Problem* (Springfield, Ill.: Charles C Thomas, 1962), 51; “Heroin Hydrochloride,” *JAMA* 47 (1906): 1303. David T. Courtwright, “The Roads to H: The Emergence of an American Heroin Complex, 1898-1956,” in *One Hundred Years of Heroin*, ed. David F. Musto et al. (Auburn House: Westport, Conn., 2002), 4-5, describes early debates over heroin’s appropriate therapeutic uses.

Many articles have appeared in medical literature during the last two years lauding this new agent, and doubtless much can be truthfully said in its favor, but some who have written in its praise seem to have been misled by the claim of its promoters, that even its prolonged use does not result in the formation of a habit.

When we consider the fact that Heroin is a morphine derivative, being the diacetyl of morphine, and that in this form it retains almost all of the properties of the salt from which it is derived, it does not seem reasonable that such a claim could be well founded. It is strange that such a claim should mislead any one [sic] or that there should be found among the members of our profession those who would reiterate and accentuate it without first subjecting it to the most critical tests, but such is the fact.

Dr. Pettey reviewed five previously published accounts by physician "promoters" who claimed that heroin either carried no risk of habit formation or was useful in treating morphine addiction. Reading the reports with an eye for clinical details, he saw that the findings did not add up. The patients had either been treated with heroin in hospitals following surgery (which is to say in a controlled environment and for a limited period of time) or as outpatients for "a few days." In most instances the authors had not specified the length of treatment, or the length of time they had followed up the patients, so their assertions about the safety of heroin's "continued use" were impossible to prove.

As for the salvation of morphine addicts, Dr. Pettey reviewed records of 150 drug addicts who had come under his care. Eight used heroin, but only three of these cases had begun with the drug. Another had been an abstinent morphine addict who relapsed when given heroin by a well-intentioned surgeon following a painful operation. "The other four cases were morphine users

who had substituted Heroin for morphine with the idea that they were curing themselves of the habit, but after the substitution was made they were unable to leave off the Heroin.” The conclusion was obvious: “Be not deceived, it is an opiate.”<sup>23</sup>

## **II. The Institutionalization of Narcotic Conservatism**

### **A. Lessons Reinforced: Education, Law, and Regulation, 1895-1986**

The principal benefit of such wariness, of not being deceived by ill-considered therapeutic advice or puffery, was the avoidance of new cases of addiction. This was why Drs. Scheffel, Kolb and Remig, and Pettey found that only 1.7 percent (6 of 350) of the addiction cases they collected originated in therapeutic heroin use. Of even greater benefit, though, was narcotic conservatism’s effect on iatrogenic morphine addiction, the main source of the problem. The 1895-1915 decline in the number of opiate addicts depicted in Appendix B occurred because doctors were creating fewer new addicts, even as existing addicts became abstinent or, more typically, succumbed to age, illness, or overdose. The decline in prevalence had a demographic tailwind, at least for medical addicts who were sicker and older than the younger and less sympathetic “pleasure users” who occupied, by default, an increasingly conspicuous place in the changing American narcotic landscape.<sup>24</sup>

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<sup>23</sup> George E. Pettey, “The Heroin Habit Another Curse,” *Alabama Medical Journal* 15 (1903): 174-180, capitalization thus.

<sup>24</sup> Charles E. Sceleth and Sydney Kuh, “Drug Addiction,” *JAMA* 82 (1924): 679 (“pleasure users”). “Fifteen or twenty years ago,” Sceleth and Kuh noted, “most addicts acquired the habit

By the turn of the century, then, the American medical profession had absorbed a crucial lesson in primary prevention. For most of the twentieth century that lesson was reinforced by medical educators, legislators, and federal officials, whose combined efforts reduced the therapeutic exposure of opiate-naïve pain patients and thus lowered the risk of medical opiate addiction. Lowered, but not eliminated. For example, in New York City in the 1950s an addict with the right connections could pay \$25 to a doctor to write a prescription for Dilaudid (“drugstore heroin”) and another \$25 to a pharmacist to get it filled. But this sort of arrangement was expensive. Moreover, physicians and pharmacists who skirted the law—typically to supply respectable white rather than minority or “street” users—were essentially providing maintenance doses for existing addicts, not creating new ones. More worrisome were periodic attempts by pharmaceutical manufacturers to break into the large pain market by making misleading claims about the safety of new narcotic analgesics. These attempts, however, were checked by federal regulators. Authorities presented a consistent message, backed by force of law: Minimize narcotic exposure.<sup>25</sup>

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through physical disease or discomfort. Today the number of new addictions through physicians' prescriptions is small. The great majority of cases now result from association with addicts, following their advice in taking a ‘shot’ or a ‘sniff’ for ‘what ails you’ and searching for new sensations.”

<sup>25</sup> David T. Courtwright, Herman Joseph, and Don Des Jarlais, *Addicts Who Survived: An Oral History of Narcotic Use in America before 1965*, rev. ed. (Knoxville: University of Tennessee Press, 2012), 174-175 (Dilaudid prescription). David Herzberg, “Entitled to Addiction? Pharmaceuticals, Race, and America’s First Drug War,” *Bulletin of the History of Medicine* 91

In a word, narcotic conservatism was institutionalized. Medical, legislative, regulatory, and philanthropic institutions pulled at the same supply-reduction oar, which is why historians refer to the mid-twentieth century as “the classic era of narcotic control.” This section offers several examples of those institutional efforts and shows how they reinforced and perpetuated the narcotic conservatism that emerged in the late nineteenth and early twentieth century.<sup>26</sup>

The starting point for narcotic conservatism was medical education. Standard texts emphasized that symptomatically treating *any* form of dysmenorrhea with opiates ran the risks of addiction and professional condemnation. “He who is compelled to resort frequently to opium and stimulants,” the authors of *An American Text-Book of Gynecology* wrote in 1898, “must be considered devoid in diagnostic ability, and consequently ought not to be entrusted with the

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(2017): 586-623, and Courtwright, *Dark Paradise*, 136-137, describe covert physician maintenance. It should be noted that not all New York City pharmacists were obliging or corruptible. In 1955 William S. Burroughs recalled an encounter with a druggist whom he had asked to fill a prescription for relatively mild codeine tablets. “His *pince-nez* falls off. Then he calls the doctor (but can’t find him in), asks questions, finally refuses to fill the script without talking to the doctor. Codeine!!” Burroughs to Allen Ginsberg, April 20, 1955, *The Letters of William S. Burroughs, 1945-1959*, ed. Oliver Harris (New York: Viking, 1993), 273.

<sup>26</sup> Historians who have used “the classic era” as a chronological framework and reference point include Courtwright, Joseph, and Des Jarlais, *Addicts Who Survived*, 1-44; Caroline Jean Acker, *Creating the American Junkie: Addiction Research in the Classic Era of Narcotic Control* (Baltimore: Johns Hopkins University Press, 2002), 1-12; and Herzberg, “Entitled to Addiction?”

management of such cases.” Professors boasted in print of how infrequently they prescribed opiates and reiterated the need to carefully monitor patients. I am a neurologist, Dr. William J. Herdman told his students in 1902. I see more pain than most. Yet I write far fewer prescriptions for potent narcotics than the average general practitioner and still get better results.<sup>27</sup>

Rank-and-file practitioners noted the pedagogical trend. The teaching now, Tennessee physician T.J. Happel wrote in 1895, was “when in doubt..., do not give it.” C.W. Bonyge, a Los Angeles police surgeon, attributed the decline in medical addiction to “teachers of Material Medica [Pharmacology] and the text books [being] very persistent in their warnings of the danger.” Dr. Oscar C. Young, in a 1901 paper before the New Hampshire medical society, said that new doctors had been so thoroughly warned about the dangers of opiates in their medical school lectures and ward rounds that their patients might endure “agonies worse than any hell for want of one-eighth of a grain of morphine.”<sup>28</sup>

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<sup>27</sup> Henry T. Byford et al., *An American Text-Book of Gynecology*, second rev. ed. (Philadelphia: W.B. Saunders, 1898), 105; Walter F. Boggess, “Morphinism,” *Medical Age* 17 (1899): 883; Herdman comment on C.B. Burr, “Concerning Morphine Addiction and Its Treatment,” *JAMA* 39 (1902): 1592.

<sup>28</sup> T.J. Happel, “The Opium Curse and Its Prevention,” *Medical and Surgical Reporter* 72 (1895): 728; Bonyge to Hamilton Wright, August 12, 1908, box 29, USIOC; Oscar C. Young, “On the Use of Opiates, Especially Morphine,” *Medical News* 80 (1902): 154.

This was putting the matter too strongly. Narcotic conservatism was never narcotic nihilism. The proper standard of care, as Dr. Blair explained, was to limit opiate prescribing to cases involving emergencies, trauma, surgery, and acute or terminal pain. This concept of limited use too found a home in mid-century medical textbooks. The flagship was Louis Goodman and Alfred Gilman's *The Pharmacological Basis of Therapeutics*, published in 1941 and thereafter updated and reissued as the standard authority in the field. Goodman and Gillman emphasized the importance of using minimum effective doses for specific conditions, such as shock following trauma or acute pain arising from biliary colic. Even then the patient should never be told that he was receiving an opiate, never be entrusted with hypodermic means of administration, and never be given a prescription for more than necessary for "a short interval" of treatment before again seeing the physician. Should this interval last "several days," the physician was to observe closely "after cessation of therapy to discover whether he is addicted." This addiction risk underscored Goodman and Gilman's summary judgment: "The physician should never employ a narcotic when another drug will accomplish the same end."<sup>29</sup>

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<sup>29</sup> Louis Goodman and Alfred Gilman, *The Pharmacological Basis of Therapeutics: A Textbook of Pharmacology, Toxicology and Therapeutics for Physicians and Medical Students* (New York: Macmillan, 1941), 217-221, quotations p. 217, and Caroline Jean Acker, "From All-Purpose Anodyne to Marker of Deviance: Physicians' Attitudes towards Opiates in the US from 1890 to 1940," in *Drugs and Narcotics in History*, ed. Roy Porter and Mikuláš Teich (Cambridge: Cambridge University Press, 1995), 128. Acker adds that, after 1928, the American Medical Association routinely communicated with federal authorities and state licensing boards

Lecturers and attending physicians stressed another core lesson, the importance of minimizing and monitoring the dose when opiates were indicated. “We were all—nurses, pharmacists, physicians—taught: Don’t overdose, don’t overdose, don’t overdose,” said Martha Stanton, a nurse trained in the 1960s and 1970s. “You give the smallest amount of medication over the longest period of time because you don’t want to give a patient too much, for fear of addiction.”<sup>30</sup>

More specialized studies dealing with pain and its management also stressed the need for caution. The chapter on analgesia in *Chronic Pain*, a comprehensive anthology edited by specialists at the Duke University Medical Center, reflects the wariness still prevailing in the mid-1980s:

In patients with chronic benign states who have anxiety, depression, and/or severe character pathology, the potential for abuse is high and opioid drugs are not effective drugs for the management of pain. Similarly, caution should be exercised in prescribing opioid analgesics to patients who have a history of substance abuse. Informed consent from the patient should be obtained before using opiates for the management of chronic pain. The patient needs to have a clear understanding of the possible side effects, habituation, and physical dependency that may occur with opioid drugs. More potent

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to identify physicians “convicted for violating the Harrison Act so that evocation of licensure and publication of the offenders’ names in *JAMA* might prevent their resuming their practices” (124).

<sup>30</sup> Sam Quinones, *Dreamland: The True Tale of America’s Opiate Epidemic* (New York: Bloomsbury Press, 2016), 94 (Stanton).

opioid analgesics (methadone, morphine, oxycodone) should be used only when weaker opioid analgesics do not provide effective pain control. Regular follow-up visits are essential to monitor dose, to prevent or minimize tolerance, and to monitor side effects. The goal is to establish the lowest effective maintenance dose with a minimum of side effects.

Guidelines from the Federal Bureau of Narcotics [sic; the old name for what was by then the Drug Enforcement Administration] state that physicians may use narcotics to relieve acute pain. Physicians directly in charge of patients suffering from a chronic disease can use opioid analgesics for the relief of pain over an extended period if the doses are kept within limits accepted by other physicians, and if proper care and reasonable precautions are taken to prevent illicit diversion of the drugs. It is advisable that physicians document the indication for continuous use, maintain records of the drug use, and obtain consultation for the use of opioid analgesics in chronic pain patients.

Advice books aimed at lay readers contained even blunter warnings. “Narcotics should not be used to manage chronic nonmalignant pain,” summed up one. “Their negative consequences usually outweigh any positive benefits.”<sup>31</sup>

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<sup>31</sup> Randal D. France, K. Ranga Rama Krishnan, and Ananth N. Manepalli, “Analgesics in Chronic Pain,” in *Chronic Pain*, ed. Randal D. France and K. Ranga Rama Krishnan (Washington, D.C.: American Psychiatric Press, 1988), 438. Though the imprint is 1988, the chapter contains no references postdating 1984, suggesting that it was composed around 1985 and subsequently published with the other chapters. See also Richard W. Hanson and Kenneth E.

If professional opinion sustained and strengthened narcotic conservatism during most of the twentieth century, so did Congress, courts, and administrators. The legal and policy pattern from 1906 to 1986 was one of increasingly tight control of supply and increasingly strict punishment of violators, punctuated by brief counter-cycles of liberalization. A timeline and summary of key federal legislative, judicial, and administrative developments from the first protective law to the current governing statute, the CSA, makes the trend clear:

**1906** Pure Food and Drug Act. Created labeling requirements for ingredients, such as narcotics or alcohol, that were potentially toxic and addictive.

**1909** Smoking Opium Exclusion Act. Banned all imports of opium prepared for smoking.

**1912** Hague Opium Convention. Laid the groundwork for a system of international narcotic control in which supply was to be limited to estimated medical and scientific needs. The treaty pledged signatories, which included the United States, to enact and enforce laws to control domestic manufacture and sale of medicinal narcotics. Subsequent diplomacy, led by the United States, tightened international production controls, culminating in the 1953 Opium Protocol.

**1914** Harrison Narcotic Act. Required all who dealt in narcotic drugs, from manufacturers and wholesalers to physicians and pharmacists, to register with the Treasury Department, to pay a small tax, and to keep accurate records of their transactions. Nominally a revenue law, the goal

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Gerber, *Coping with Chronic Pain: A Guide to Patient Self-Management* (New York: Guilford, 1990), 37 (quotation).

was to make commerce in opiates and cocaine transparent and to confine it to legitimate medical channels. Transactions outside medical channels were subject to criminal prosecution.

**1919** Volstead Act. Reduced spirituous beverages to the status of prescription drugs and increased federal law enforcement capacity. Voided by Repeal in 1933.

**1919** U.S. Supreme Court rulings in *United States v. Doremus* and *Webb et al. v. United States*. The former affirmed the constitutionality of the Harrison Act's exercise of the federal police power to control narcotic commerce. The latter reversed an earlier Supreme Court decision and ruled that a physician or pharmacist registered under the Harrison Act might not provide opiates for the sole purpose of sustaining an addict's habit, a practice known as "maintenance."

**1919-1921** Treasury Department closure of most municipal narcotic clinics. The closures frustrated the attempts of more than thirty cities to provide institutional maintenance of addicts as an alternative to physician prescriptions or the black market.

**1922** Jones-Miller Act. Established the Federal Narcotics Control Board to oversee and regulate the import and export of narcotics and increased maximum penalties for narcotic law violations. Opiate imports were forbidden for other than medical purposes, and exports limited to nations with adequate licensing and control systems.

**1924** Heroin Act. Forbade the importation of opium for the manufacture of heroin.

**1928** Committee on Drug Addiction (CDA) established by the National Research Council. Originally focused on an attempt, ultimately unsuccessful, to find a non-addictive narcotic analgesic, the CDA (rechristened CDAN, the Committee on Drug Addiction and Narcotics)

evolved into a skeptical referee of pharmaceutical companies' claims about the toxicity and addiction potential of new narcotic preparations.

**1929** Porter Act. Funded two federal narcotic prison-hospitals (or "farms") that opened in Lexington, Kentucky, in 1935 and in Fort Worth, Texas, in 1938. The former also housed the Addiction Research Center (ARC), whose researchers used patient volunteers to evaluate claims about the addiction liability of new narcotics before they were marketed.

**1930** Federal Bureau of Narcotics (FBN). Consolidated the functions of the Treasury Department's Narcotic Division and the Federal Narcotics Control Board in a new agency headed by Harry Anslinger. As director from 1930 to 1962, Anslinger pursued a strict but consistent supply-control policy aimed at limiting pharmaceutical production, minimizing diversion, interdicting trafficking, suppressing nonmedical use, isolating addicts, forbidding maintenance, and punishing violators with mandatory minimum sentences.

**1937** Marijuana Tax Act. Brought marijuana, by then prohibited in several states and cities, into the realm of federal narcotic control.

**1938** Food, Drug and Cosmetic Act. Replaced and strengthened the 1906 legislation, adding requirements that manufacturers include directions for safe use, secure pre-marketing approval for new drugs shown to be safe, and refrain from making false therapeutic claims.

**1951** Durham-Humphrey Amendment to the Food, Drug, and Cosmetic Act. Clarified the definition of prescription drugs as those that were habit-forming or sufficiently toxic to require medical supervision, including new drugs approved under the safety provisions of the 1938 law.

that warranted medical supervision. Required prescription drugs to bear a label, “Caution: Federal law prohibits dispensing without prescription.”

**1951** Boggs Act. Imposed lengthy mandatory minimum sentences for narcotic possession and sale convictions; inspired “Little Boggs Laws” in states that imposed minimum sentences that matched or exceeded federal levels.

**1956** Narcotic Control Act. Further increased fines and mandatory minimum sentences; made possible the death penalty in cases involving sales to minors.

**1962** White House Conference on Narcotics and Drug Abuse. Raised possibility of less punishment and more treatment for heroin addicts and addressed the need to bring widely abused non-narcotic drugs (e.g., barbiturates, amphetamines) under tighter control.

**1965** Drug Abuse Control Amendments. Limited the number of refills for a single prescription and imposed stricter record keeping by manufacturers, distributors, pharmacists, and physicians who dispensed drugs directly. Created within the FDA a new Bureau of Drug Abuse Control (BDAC).

**1968** Bureau of Narcotics and Dangerous Drugs (BNDD). Formed by a merger of the FBN and BDAC and relocated in the Department of Justice, the BNDD was the nation’s lead drug enforcement agency until 1973, when Congress authorized further mergers to create the Drug Enforcement Administration (DEA).

**1970** Controlled Substances Act (CSA). Rationalized and reformed the accumulated drug-control legislation into what Attorney General John Mitchell called “one body of organic law.” The

centerpiece of the CSA was the scheduling system, which allowed the FDA in consultation with BNDD (later DEA) to sort drugs into five categories according to their therapeutic value and abuse potential. Schedule I drugs were prohibited. Schedule II drugs, which included medical narcotics like Dilaudid or oxycodone, were the most tightly regulated. They warranted no prescription refills, triplicate order forms for transfers, BNDD production quotas, enhanced storage security requirements, and BNDD preapproval for all imports and exports.<sup>32</sup>

The CSA formalized and further strengthened the closed system of distribution that had been evolving for over half a century. “Closed” meant that transactions could lawfully occur only among authorized registrants, typically when a registered manufacturer sold to a registered

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<sup>32</sup> Mitchell to House Speaker John W. McCormack, July 15, 1969, “Comprehensive Drug Abuse Prevention and Control Act,” vertical files, Drug Enforcement Administration Library, Arlington, Va., (quote) and Kenneth C. Baumgartner and Michael X. Morrell, “Pharmaceutical Industry Regulation by the Department of Justice,” *Syracuse Law Review* 23 (1972): 203-205 (Schedule II procedures). The timeline and summaries draw on Acker, *Creating the American Junkie*; Richard J. Bonnie and Charles H. Whitebread II, *The Marijuana Conviction: A History of Marijuana Prohibition in the United States* (New York: Lindesmith Center, 1999); Courtwright, *Dark Paradise*; Courtwright, Joseph, and Des Jarlais, *Addicts Who Survived; Federal Drug Control: The Evolution of Policy and Practice*, ed. Jonathon Erlen and Joseph F. Spillane (New York: Pharmaceutical Products Press, 2004); David Herzberg, *Happy Pills in America: From Miltown to Prozac* (Baltimore: Johns Hopkins University Press, 2009); and David F. Musto, *The American Disease: Origins of Narcotic Control*, 3<sup>rd</sup> ed. (New York: Oxford University Press, 1999).

distributor, which in turn supplied a registered retail pharmacy, which in turn supplied the ultimate consumer, a patient possessing a legitimate prescription issued by a registered medical or dental practitioner. Scheduled drugs were to remain under the control of registrants, and only registrants, until such time as they reached their intended medical users.<sup>33</sup>

From the year the CSA took effect (1971), registrants were charged with safeguarding the redesigned system as well as following its procedures. The *Code of Federal Regulations* spelled out several responsibilities. Registrants were to implement storage and shipping security controls to prevent diversion. They were to immediately report “any significant loss of any controlled substances.” They were to make good-faith inquiries to determine that their customers had registered with DEA. And they were to “design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.”<sup>34</sup>

In historical and legal terms, the CSA was the finishing touch on a drug-control system that the federal government had been building since the Progressive Era of the early twentieth

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<sup>33</sup> Brian T.Yeh, “The Controlled Substances Act: Regulatory Requirements,” Congressional Research Service, December 13, 2012, p. 4, <https://fas.org/sgp/crs/misc/RL34635.pdf> (“closed”).

<sup>34</sup> 21 CFR Ch. II (April 1, 1996 edition) §§ 1301.73, 1301.74,  
<https://www.gpo.gov/fdsys/pkg/CFR-1996-title21-vol9/pdf/CFR-1996-title21-vol9-sec1301-74.pdf>.

century. The system was meant to protect the American public against illicit traffickers as well as licit pharmaceutical manufacturers and distributors who might be tempted to employ irresponsible advertising and sales practices.

Federal regulators remained vigilant after the CSA's 1970 enactment. Though most of the media attention fell on Congressional hardening of the CSA to combat illicit drugs (for example, by amendments passed in 1980, 1986, and 1988 that imposed stricter punishments for Schedule I trafficking offenses), regulators continued to ratchet up controls over the licit trade. Between 1970 and 1977 they scheduled thirty-five additional drugs, including so-called minor tranquilizers. They rescheduled eight others, mostly amphetamines and barbiturates, by moving them up into Schedule II. The six drugs that were decontrolled were mostly narcotic antagonists—that is, drugs that *reversed* the effects of narcotics.<sup>35</sup>

### **B. Illustration: The Federal Control of Methadone and Oxycodone, 1946-1974**

A key reason that the federal government had to keep adjusting the drug-control system was that the pharmaceutical industry kept developing potent new psychoactive drugs, including synthetic and semi-synthetic opiates. These innovations were not necessarily bad. As the preamble to the CSA states, drugs in schedules II through V had legitimate and healthful benefits

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<sup>35</sup> David T. Courtwright, "The Controlled Substances Act: How a 'Big Tent' Reform Became a Punitive Drug Law," *Drug and Alcohol Dependence* 76 (2004): 9-15; U.S. Department of Justice, *Summary of Drug Control Actions Under the Controlled Substances Act of 1970* (Washington, D.C.: DEA Office of Compliance and Regulatory Affairs, 1977).

when properly used, “substantial and detrimental” harms when improperly used. The object of policy was to regulate drugs in a way that maximized their health benefits while minimizing their harms. But this public goal was in tension with the profit-making aims of the makers and distributors of psychoactive drugs. Maximum profit, particularly in a large market like CNP patients, required minimizing regulatory restrictions and oversight.<sup>36</sup>

The result was a cat-and-mouse game that played out during the postwar decades. When it came to opiates, the cat—the federal government—usually won. Methadone, for example, was heavily regulated before, during, and after the maintenance revolution of the 1960s and early 1970s. Knowledge of how to make methadone, manufactured by I.G. Farben during World War II, arrived in the United States as part of the postwar haul of German scientific and technical information. Where FBN officials saw danger, drug companies saw opportunity. Firms like Eli Lilly, Abbott, and Winthrop wanted to bring the drug to market as a synthetic analgesic. The FBN wanted to limit its manufacture and distribution because CDAN experiments proved the drug to be addictive.

The experiments included trials on an unspecified but reportedly large number of detoxified narcotic addicts in federal institutions. Investigators reported that

Most of the men expressed satisfaction with the effects of the drug as long as 10-mg doses, or higher, were given. The greater the dose given the greater the satisfaction expressed by the addicts. Most subjects stated that the effects were similar to those of

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<sup>36</sup> *Statutes at Large, 1970-1971*, vol. 84, part 1 (Washington, D.C.: Government Printing Office, 1971), public law 91-513.

morphine, heroin, or dilaudid [sic], but were slower to develop. Intravenous doses produced the greatest degree of satisfaction.

Definite euphoria has been observed in a large number of cases following the injection of amidone [i.e., methadone, also called Dolophine]. The patients became more talkative, boasted of their exploits, asked for more of the drug, and attempted to devise ways to get even more. Typical comments following injection of the drug were ‘That is great stuff. I wouldn’t have believed it possible for a synthetic drug to be so like morphine. Can you get it outside? Will it be put under the narcotic laws? I wish I could get some to kick my next habit with.’

The last remark was prescient. Because methadone was long-acting when taken orally, it turned out to be useful for tapering addicts during withdrawal. More controversially, it could be used for long-term maintenance, as Drs. Vincent Dole and Marie Nyswander were to show in the 1960s. But in 1946 the men’s comments were simply taken as evidence “that narcotic drug addicts would abuse methadon [sic] and would become habituated to it if were freely available and not controlled.”<sup>37</sup>

More alarming was the prospect, which Anslinger outlined in high-level meetings in April 1947, that numerous pharmaceutical companies, which had filed new drug applications

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<sup>37</sup> Quotation from “Tolerance and Addiction Liability of 4, 4-Diphenyl-6-Dimethylamino-Hepatone-3” (TS, 1947), “Amidone Investigation,” file 0480-203A [hereafter Amidone file], Records of the Drug Enforcement Administration, RG 170, National Archives II, College Park, Maryland.

with the FDA and expressed their intentions to manufacture “about ten times the quantity for any possible medical need,” would create a huge surplus that “would find its way into abusive use.” Unleashing a tidal wave of prescription opiates, which the manufacturers could not possibly safeguard from diversion, would create new addicts and sustain existing addicts, a risk insofar as they might recruit and supply others. CDAN’s experts unanimously agreed “that such overproduction would inevitably be reflected in the spread of drug addiction.” Unfortunately, a primary means to prevent oversupply, the FBN’s ability to impose production quotas, had been called into legal question. Methadone was a synthetic drug. It was not derived from opium. Hence it was arguably not subject to the usual narcotic manufacturing controls.<sup>38</sup>

The industry lost the argument. On July 31, 1947, following a round of reports and public hearings, President Harry Truman issued a proclamation that methadone had “an addiction-forming and addiction-sustaining liability similar to morphine.” It was thus an opiate and thus subject to federal controls over manufacturing, distribution, and prescribing. The FBN then directed that the drug be dispensed with the same medical and pharmaceutical care as morphine. Physicians were to report all cases of methadone addiction “whether primary or sustained … to the Bureau with as complete a history of the of the circumstances as possible.” The FBN also flatly denied Eli Lilly’s request “to give free of charge to those [physicians] who request it, a tube of ten of the 5-milligram size tablets and a two-ounce bottle of the cough syrup, containing

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<sup>38</sup> CDAN meeting minutes of April 15, 1947 (Anslinger quotations) and April 22, 1947; Lewis H. Weed to Secretary of the Treasury John W. Snyder, April 24, 1947 (“spread”), all Amidone file.

10 milligrams ‘Dolophine’ in each 30 cc.” Orally administered or not, there would be no free samples.<sup>39</sup>

Worries about methadone abuse and diversion were not confined to the 1940s. They cropped up again in the early 1970s. Public health officials in New York and other cities, with the support of the Nixon administration, were then rapidly expanding methadone maintenance programs. Though methadone maintenance did improve the health and behavior of individual addicts, it also entailed a risk, publicized by national media, of diversion and overdose deaths. The FDA and the BNDD responded with new dispensing and take-home rules, clinic inspections, and demands for tighter security. In 1974 this diffuse regulatory reaction was codified in the Narcotic Addict Treatment Act. The act amended the CSA which, as noted above, became a more restrictive and punitive law during the 1970s and 1980s.<sup>40</sup>

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<sup>39</sup> “Drug Amidone an Opiate” (TS, 1947), subsequently printed and dated in *Statutes at Large*, vol. 61, part 2 (Washington, D.C.: Government Printing Office, 1948), 1075; “General Circular No. 181” (TS, 1947); and I.H. Small to Will S. Wood, September 9, 1947, and Wood to Small, September 15, 1947, all Amidone file.

<sup>40</sup> Courtwright, Joseph, and Des Jarlais, *Addicts Who Survived*, 319-356; Committee on Federal Regulation of Methadone Treatment, Division of Biobehavioral Sciences and Mental Disorders, Institute of Medicine, *Federal Regulation of Methadone Treatment*, ed. Richard A. Rettig and Adam Yarmolinsky (Washington, D.C.: National Academy Press, 1995), chaps. 4-5. National publicity, e.g., James M. Markham, “Methadone Found Rising as a Killer: Overdose Deaths Here and in Capital Up Sharply,” *New York Times*, March 14, 1972, p. 48.

Federal regulators monitored semi-synthetic, as well as synthetic, opiates. FBN Director Anslinger and his CDAN allies insisted on independent evaluation of all opiate safety, effectiveness, and addiction liability; strictly limited opiate imports and manufacturing to medical need; and used the power to curtail opium supplies to force narcotic manufacturers to toe the line on labeling, advertising, and marketing. Anslinger in particular confronted manufacturing executives, including those whose companies made and marketed Dilaudid, Pantopon, and Demerol.<sup>41</sup>

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<sup>41</sup> David Herzberg, “Big Pharma’s Real Nemesis? Putting the FBN back into Pharmaceutical History,” paper for the American Association of the History of Medicine annual meeting, Chicago, May 10, 2014. State examining boards, which had the power to discipline physicians and suspend their licenses, also served as opioid watchdogs—in effect, mini-FBNs. In December 1953, for example, the Oregon board issued a letter and a circular, “Dangerous Addictive Properties of the Newer Narcotic Analgesics,” to every physician in the state. Physician addiction from self-medication was rising, the board warned, and 80 percent of recent cases involved synthetic narcotics. Doctors were insufficiently aware of their dangers, in part because of “publicity given to early over-optimistic claims that the synthetic analgesics were non-addictive.” To counter that misimpression, the Board described the addiction liability of the most commonly used synthetic and semisynthetic narcotics. Among them were methadone, hydrocodone, and oxycodone. Ralph E. Purvine to “Dear Doctor,” December 10, 1953, and “Dangerous Addictive Properties of the Newer Narcotic Analgesics,” file brochure (N.c.: Oregon State Board of Medical Examiners, 1953), “Synthetic Substitutes,” file 0480-76, Records of the

Anslinger also kept a watchful eye on oxycodone, the primary ingredient in Endo's preparation Nucodan. In 1949 Anslinger objected to Endo's brochure for Nucodan and referred the matter to CDAN. Endo had likened Nucodan to codeine, a relatively mild opiate, and suggested that rabbit experiments demonstrated no addiction liability. Company representatives testified that oral administration and the presence of homatropine, an anticholinergic drug, "would be a strong deterrent to addiction."

CDAN's experts, Drs. Nathan Eddy, Lyndon Small, and Harris Isbell, dismantled every assertion. The rabbit experiments (which Eddy himself had conducted) were cited out of context. The tablets could be dissolved and boiled to remove the homatropine, which in any case offered little deterrent effect. Nucodal was far closer in addiction liability to morphine than codeine, and the brochure must warn physicians up front. Endo should have been aware of the risk. German medical literature, Eddy pointed out, contained several references to addiction to Eucodal, the

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Drug Enforcement Administration, RG 170-74-12, box 3, National Archives II, College Park, Maryland.

German trade name for oxycodone. Eucodal, Anslinger added, was regarded by German and United Nations regulators as a morphine equivalent.<sup>42</sup>

As it happened, William F. Burroughs, the mid-twentieth century's self-styled "Master Addict," conducted his own trials of Eucodal. In early 1957 Burroughs published a famous letter in the *British Journal of Addiction* that cataloged his drug self-experimentation. In the opiate class he had used, in addition to Eucodal, opium, heroin, morphine, Dilaudid, Pantopon, Demerol, methadone, and other preparations of varying strengths. All had narcotic effects. All were habit-forming. "Nor does it make much difference how the drug is administered, smoked, sniffed, injected, taken orally, inserted in rectal suppositories, the end result will be the same: addiction." Two years earlier, in a letter to Allen Ginsberg (also subsequently published), Burroughs was franker. He had been injecting Eucodal and had become hopelessly strung out. "Trust the Germans," he wrote, "to concoct some really evil shit. It acts direct [sic] on nerve centers. This stuff is more like coke than morphine. A shot of Eukodal [sic] hits the head first with a rush of pleasure. Ten minutes later you want another shot. Between shots you are just killing time."<sup>43</sup>

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<sup>42</sup> "Committee on Drug Addiction and Narcotics Meetings: 5<sup>th</sup>: Minutes: 5/11/49" (TS, 1949), pp. 76-78, Committees on Drug Addiction, Drug Addiction (Advisory), and Drug Addiction and Narcotics, 1928-1965, Archives of the National Academy of Sciences, Washington, D.C.

<sup>43</sup> William S. Burroughs, "Letter from a Master Addict to Dangerous Drugs," *British Journal of Addiction* 53 (1957): 119-120, and Burroughs to Ginsberg, June 16, 1954, *Letters of William S.*

Burroughs was referring to the same drug, oxycodone, that Purdue and Teva and Mallinckrodt marketed as safe and effective, and in pills that could be dissolved and injected, to millions of Americans in the late 1990s and early 2000s. It was the same drug that Endo manufactured and sold both as a generic and as an ingredient in Percodan and Percocet. And it was the same drug that McKesson and other distributors supplied in increasing amounts to U.S. pharmacies from 2008 to 2013, even after being confronted by the DEA for failing to report suspicious bulk orders.<sup>44</sup>

I will conclude this mid-century survey by mentioning one other pertinent development, in the field of epidemiology. Using analytical statistics and growing computational power to sort through health data, researchers began to explore how exposure to various psychoactive substances affected both addiction rates and the amount of illness and premature death within a population. In 1973, for example, sociologist Philip Baridon published a study of narcotic addiction rates for thirty-three countries. He identified twelve independent variables, such as a country's wealth, urbanization, racial homogeneity, and proximity to supply. He applied multiple-regression analysis, a technique for estimating relative causal weights, and he

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*Burroughs*, ed. Harris, 215. Though the article publication date is January 1957, Burroughs composed the letter on August 3, 1956, hence two years.

<sup>44</sup> Office of Public Affairs, Department of Justice, “McKesson Agrees to Pay Record \$10 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs,” press release, January 17, 2017, <https://www.justice.gov/opa/pr/mckesson-agrees-pay-record-150-million-settlement-failure-report-suspicious-orders>.

discovered that supply proximity explained far more variance (45 percent) than any of the other eleven factors. In one way this was simply a mathematical demonstration of historical common sense. A society like late-nineteenth-century China had suffered high rates of narcotic addiction because the country was both a major producer and importer (from nearby India) of opium. But the systematic work of Baridon and other statisticians strengthened and generalized the point.

“The most fundamental fact about drug abuse is frequently overlooked in the welter of complicated psychosocial explanations,” Baridon wrote. “If the drug is not available, there will be no abuse of it.”<sup>45</sup>

The same principle applied to another potent psychoactive substance, alcohol. In the 1950s and 1960s a French demographer, Sully Ledermann, showed that many diseases and social problems closely tracked national alcohol consumption. Tuberculosis, cancers of the digestive tract, psychiatric admissions, accidents, crimes, vandalism: Their rates rose when French alcohol consumption rose, and not just among the heaviest drinkers. The findings laid bare the contradictions of French alcohol policy, then geared to promoting consumption for the sake of alcohol producers, retailers, and tax collectors. Keep on that path, Ledermann said, and you will keep on promoting alcoholism and alcohol-related mortality. Though the French initially ignored the advice, Ledermann’s ideas caught on among Scandinavian, British, and North American

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<sup>45</sup> Philip Baridon, “A Comparative Analysis of Drug Addiction in 33 Countries,” *Drug Forum* 2 (1973): 335-355, quotation p. 342.

alcohol researchers. By the mid-1970s they had made reduction in overall consumption a central goal of alcohol-control policy.<sup>46</sup>

One way to reduce consumption was to raise the legal drinking age. In 1984 the U.S. government did so by raising the minimum drinking age to twenty-one. The move was initially controversial, but the controversy faded when studies showed upwards of a thousand fewer traffic deaths a year. Some teenagers still drank, of course. But proportionately fewer of them did so, or crashed their cars, or blacked out, or suffered other adverse health consequences, notably higher rates of alcoholism, statistically associated with early and heavy drinking. The implication was clear. Supply restriction meant fewer dead and addicted kids.<sup>47</sup>

One apparent exception to the less-is-better psychoactive substance rule was methadone maintenance. As mentioned above, clinical and statistical studies from the late 1960s on showed that heroin addicts enjoyed better health and committed fewer crimes when switched to a steady

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<sup>46</sup> M. Craplet, “Policies and Politics in France: ‘From Apéritif to Digestif,’” *From Science to Action? 100 Years Later—Alcohol Policies Revisited*, ed. Richard Müller and Harald Klingemann (New York: Kluwer, 2004), 127; Virginia Berridge, *Demons: Our Changing Attitudes to Alcohol, Tobacco, and Drugs* (Oxford: Oxford U. Press, 2013), 190-191; Alex Mold, “‘Everybody Likes a Drink. Nobody Likes a Drunk’: Alcohol, Health Education and the Public in 1970s Britain,” *Social History of Medicine* 30 (2017): 612–636.

<sup>47</sup> William DeJong and Jason Blanchette, “Case Closed: Research Evidence on the Positive Public Health Impact of the Age 21 Minimum Legal Drinking Age in the United States,” *JSAD* supplement no. 17 (1984): 108-115.

daily dose of methadone. The main reason was that methadone, a legal, orally administered, and comparatively long-acting opioid, had inherent advantages over black-market heroin, which was none of these things. However, these advantages accrued to patients who were *already* confirmed addicts, not to opioid-naïve subjects who were better off if never exposed to methadone or other narcotics on a long-term basis. The public health moral was clear. Allow carefully monitored “agonist” treatment with drugs like methadone (and, later, buprenorphine) in the addict subpopulation, but minimize opioid supply and exposure in the general population, except in situations like surgery or terminal illness for which the drugs were indicated. The new dispensation of liberalized opioid prescribing, which would consign nonmalignant pain patients to the pharmacological equivalent of indefinite methadone maintenance even though they were not (yet) addicted to narcotics, thus ran contrary to the public health implications of addiction epidemiology.

## **Summary**

In 2018 Purdue Pharma took out a series of full-page ads in national newspapers that acknowledged the dangers of opioid prescribing, both to individuals and to the public health. The August 7, 2018, ad stated that “we are acutely aware of the public health risk opioid analgesics can create. And we are deeply concerned about the toll the opioid crisis is now having on individuals and communities across the nation, and as a company now led by a physician, we believe the country needs a new approach to prescribing opioids.” Purdue’s October 24, 2018, ad stated, “While opioid pain medication can help patients with acute and chronic pain when other treatment options are inadequate, we are aware of the risks of addiction, abuse, and misuse that can lead to overdose and death.” Purdue’s November 15, 2018, ad stated that, “We are acutely

aware of the risks opioid pain medicines can create: even when taken as prescribed, they carry risks of addiction, abuse, and misuse that can lead to overdose and death.”<sup>48</sup>

Informing the public that novel forms of narcotic medication carried serious and potentially lethal risks might have been news in 1870. It was not news in 2018, nor was its news in the 1980s and 1990s, when an industry-backed campaign undermined the prevailing belief that the risks of long-term use of prescription opioids in treating CNP far outweighed the benefits. In this case other expert witnesses will explain how the defendants financed and orchestrated this campaign of narcotic revisionism. My goal, as a historian, is to establish a baseline of what medical professionals knew about prescribing opioids prior to the fateful developments of the 1980s and 1990s and to survey the accumulated evidence that using opioids to treat CNP was a dangerous practice. As of the early 1980s, that evidence, available to any pharmaceutical researcher, executive, or lawyer with access to a library, included 1) thousands of documented cases of iatrogenic opiate addiction in hundreds of refereed articles in the international medical literature, arranged by subject heading in standard finding aids like *Index Medicus*; 2) anthologies that gathered medical opiate addiction cases and statistics; 3) reprint editions of classic studies that stressed the danger of medical opiate addiction; 4) scholarly and popular histories of America’s first opiate addiction epidemic; 5) authoritative medical texts that

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<sup>48</sup> Purdue Pharma, “We Make Prescription Opioids. And We Want to Limit Their Use,” *Wall Street Journal*, August 7, 2018, A5; “We Manufacture Prescription Opioids, and We’ll Continue Our Work to Address the Opioid Crisis,” *Wall Street Journal*, October 24, 2018, A5; “We Support Programs that Help Identify People at Risk for Opioid Abuse and Addiction,” *Wall Street Journal*, November 15, 2018, A5.

reiterated the importance of narcotic conservatism; 6) proclamations, schedules, and regulations in *Statutes at Large* and the *Federal Register* that defined synthetic and semi-synthetic opioids as narcotics of morphine-like effect; 7) national newspaper and periodical coverage of opioid abuse and overdoses; and 8) epidemiological research that linked psychoactive substance exposure and use to higher rates of addiction, illness, and early death.<sup>49</sup>

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<sup>49</sup> Examples of case histories, medical texts, media coverage, laws, regulations, and epidemiological and scientific studies are given above. Representative of anthologies, reprint editions, and histories then available are Kolb, *Drug Addiction; Yesterday's Addicts: American Society and Drug Abuse, 1865-1920*, ed. H. Wayne Morgan (Norman: University of Oklahoma Press, 1974); Charles E. Terry and Mildred Pellens, *The Opium Problem*, reprint ed. (Montclair, N.J.: Patterson Smith, 1970); David F. Musto, *The American Disease: Origins of Narcotic Control* (New Haven and New York: Yale and Oxford University Presses, three editions [1973, 1987, 1999]); and Edward M. Brecher and the Editors of *Consumer Reports, Licit and Illicit Drugs* (Boston: Little, Brown, 1972). Asked under oath in 2015 if he had "ever studied the history of addiction and how it has played out in the 19<sup>th</sup> and 20<sup>th</sup> centuries," Dr. Richard Sackler replied, "I'm not a student of that literature." Considering, first, that his company sold drugs derived from opium alkaloids that had a long historical association with addiction; second, that the association was documented, accessible, and pertinent; and, third, that Dr. Sackler was trained in medicine, a profession that makes retrospective analysis of mistakes and failures a priority (as in morbidity and mortality conferences), his professed indifference was baffling. Richard Sackler deposition in Commonwealth of Kentucky v. Purdue Pharma L.P., et al., August 28, 2015, PPLP004030499.

Put another way, the pharmaceutical industry in the early 1980s confronted four realities. First, tens of millions of Americans suffered from some form of chronic pain for which no sure and convenient treatment was available. Second, despite a half century of trying, researchers had failed to find the holy grail of a non-addictive narcotic analgesic. No drug was to morphine what Novocain was to cocaine: a pain-deadener that did not also produce brain reward, tolerance, and potential addiction. Third, any company that successfully marketed a narcotic analgesic *as if it were this grail* could realize a substantial profit. Fourth, conventional medical opinion and federal regulators regarded any such attempt as, respectively, unethical or unlawful. Narcotic conservatism stood in the way of market expansion. Absent a genuine discovery of a non-addictive narcotic analgesic, profit maximization required that narcotic conservatism be vanquished.

Respectfully submitted, •

  
David T. Courtwright, Ph.D.

Date: March 21, 2019

## APPENDIX A: DAVID T. COURTWRIGHT, CURRICULUM VITAE

### POSITIONS AND TITLES

**Presidential Professor**, University of North Florida, 2005-2019; prof. of history since 1988.  
Voted emeritus status, effective April 2019.

**Associate Professor of History**, University of Hartford, 1985-1988.

**Assistant Professor of History**, University of Hartford, 1979-1985.

**Assistant Clinical Professor of Community Medicine**, University of Connecticut Health Center, 1981-1988, concurrent with the University of Hartford appointment.

**Faculty Associate in Epidemiology**, University of Texas School of Public Health, 1978-1979.

### EDUCATION

**Ph.D.** Rice University, History, 1979. Dissertation: “Opiate Addiction in America, 1800-1940.”

**B.A.** University of Kansas, English, *summa cum laude* and Phi Beta Kappa, 1974.

### SELECTED AWARDS AND HONORS

**NEH:** Public Scholar Grant, 2016-2017 (to write *The Age of Addiction*); Fellowship, 1998-1999 (to write *Forces of Habit*).

**University of Richmond:** Douglas Southall Freeman Professor of History, 2015.

**UNF:** John A. Delaney Presidential Professorship, 2005; Outstanding Scholarship Award, 2002, 2012; Teaching Awards, 1998, 1999, 2001, 2002, 2005; Distinguished Professor, 1998.

**College on Problems of Drug Dependence:** Media Award, 2002 (for *Forces of Habit*).

**American Council of Learned Societies:** Fellowship, 1993-1994 (to write *Violent Land*).

## **BOOKS BEARING ON THE HISTORY OF DRUG USE AND DRUG POLICY**

*The Age of Addiction: How Bad Habits Became Big Business* (Belknap Press of Harvard University Press, May 2019).

*Addicts Who Survived: An Oral History of Narcotic Use before 1965*, rev. ed. (Tennessee, 2012).

*No Right Turn: Conservative Politics in a Liberal America* (Harvard, 2010).

*Forces of Habit: Drugs and the Making of the Modern World* (Harvard, 2001).

*Dark Paradise: A History of Opiate Addiction in America*, exp. ed. (Harvard, 2001).

*Violent Land: Single Men and Social Disorder from the Frontier to the Inner City* (Harvard, 1996).

## **REFEREED ARTICLES AND CHAPTERS ON DRUGS, ALCOHOL, AND TOBACCO**

“Preventing and Treating Narcotic Addiction—A Century of Federal Drug Control,” *New England Journal of Medicine* 373 (2015): 2095-2097.

“The Prescription Opioid and Heroin Crisis: A Public Health Approach to an Epidemic of Addiction,” *Ann. Rev. of Public Health* 36 (March 2015): 559-574; second author.

“Addiction and the Science of History,” *Addiction* 107 (2012): 486-492, reprinted with commentaries and my response in “Addiction, History, and Historians: A Symposium,” *Points*, <https://pointsadhsblog.wordpress.com/2012/03/02/addiction-and-historians-a-symposium/>.

“Modernity and Anti-Modernity: Drug Policy and Political Culture in the United States and Europe in the Nineteenth and Twentieth Centuries,” *Drugs and Culture: Knowledge, Consumption and Policy*, ed. Geoffrey Hunt et al. (Farnham: Ashgate, 2011), 213-224; principal author.

“The NIDA Brain Disease Paradigm: History, Resistance, and Spinoffs,” *BioSocieties* 5 (2010): 137-147.

“Mr. ATOD’s Wild Ride: What Do Alcohol, Tobacco, and Other Drugs Have in Common?”  
*Social History of Alcohol and Drugs* 20 (2005): 105-140, with commentaries.

“‘Carry on Smoking’: Public Relations and Advertising Strategies of American and British Tobacco Companies since 1950,” *Business History* 47 (2005): 421-432.

“The Controlled Substances Act: How a Big Tent Reform Became a Punitive Drug Law,” *Drug and Alcohol Dependence* 76 (2004): 9-15.

“The Roads to H: The Emergence of the American Heroin Complex, 1898-1956,” *100 Years of Heroin*, ed. David F. Musto et al. (Westport, Conn.: Auburn House, 2002), 3-19.

“Morality, Religion, and Drug Use,” *Morality and Health*, ed. Allan M. Brandt and Paul Rozin (New York: Routledge, 1997), 231-250.

“The Prepared Mind: Marie Nyswander, Methadone Maintenance, and the Metabolic Theory of Addiction,” *Addiction* 92 (1997): 257-265.

“The Rise and Fall and Rise of Cocaine in the United States,” *Consuming Habits: Drugs in History and Anthropology*, ed. Jordan Goodman, Paul E. Lovejoy, and Andrew Sherratt (London: Routledge, 1995), 206-228, revised and republished in 2nd ed., 2007.

“The Hidden Epidemic: Opiate Addiction and Cocaine Use in the South, 1860-1920,” *Journal of Southern History* 49 (1983): 57-72.

“Opiate Addiction as a Consequence of the Civil War,” *Civil War History* 24 (1978): 101-111.  
Awarded the Mary Hayes Ewing Publication Prize in Southern History, 1979.

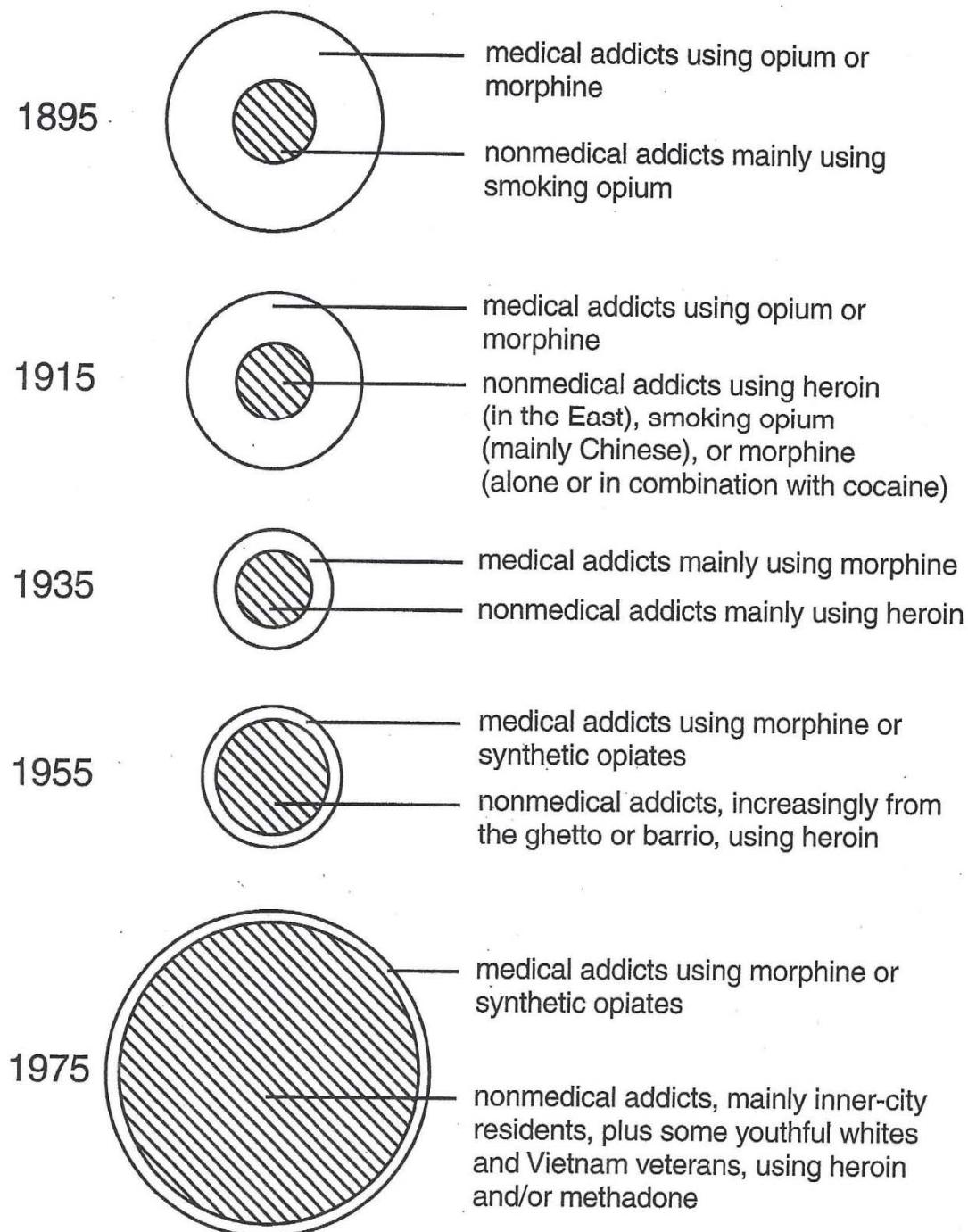
## RELATED PROFESSIONAL ACTIVITIES

President, Alcohol and Drugs History Society, 2009-2011.

Editorial Board, *Bulletin of the History of Medicine*, 2017-present.

Member, Institute of Medicine Substance Abuse Coverage Committee, 1988-1990. The committee investigated the adequacy of drug abuse treatment in the U.S. and made recommendations to Congress in *Treating Drug Problems*, 2 vols. (Washington, D.C.: National Academy Press, 1990, 1992).

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**Appendix B: Prevalence and Characteristics of U.S. Opiate Addicts, 1895-1975**

Appendix B, continued: Though contemporary prevalence estimates varied, reanalysis of available data indicates that there could not have been more than approximately 300,000 addicts

in 1895, the peak of the first U.S. epidemic. By 1975 there were approximately 600,000 addicts, overwhelmingly nonmedical heroin users, up from around 100,000 in 1967. “In those days … it wasn’t ‘the drug problem,’” commented Dr. Robert DuPont, the first director of the National Institute on Drug Abuse, “it was ‘the heroin problem.’”<sup>50</sup>

The outstanding characteristic of the epidemic that commenced after 1995, apart from its unprecedented scale, was its reversion to the older pattern of most addicts becoming addicted through prescription drugs rather than illicit “street” drugs. The current NIDA director, Dr. Nora Volkow, has estimated that there were “2.1 million people in the United States suffering from substance use disorders related to prescription opioid pain relievers in 2012 and an estimated 467,000 addicted to heroin.” If one were to add a circle for 2012 to Appendix B, it would resemble the medical/nonmedical pattern for 1895—save that it would be at least four times as large.<sup>51</sup>

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<sup>50</sup> Appendix B is adapted from Courtwright, *Dark Paradise*, Figure 13, p. 183. See *idem*, chaps. 1, 6, and 7, for the statistical basis of the demographic generalizations and prevalence estimates. The DuPont quotation is on p. 171. Around 100,000 in 1967: John C. Ball, David M. Englander, and Card D. Chambers, “The Incidence and Prevalence to Opiate Addiction in the United States,” in John C. Ball and Carl D. Chambers, eds., *The Epidemiology of Opiate Addiction in the United States* (Springfield, Ill.: Charles C Thomas, 1970), 68-78. This study is also available online at <https://pdfs.semanticscholar.org/9fae/bc71c2f4e43ceb65b8aebd333b01a52b76f1.pdf>.

<sup>51</sup> Nora D. Volkow, “America’s Addiction to Opioids: Heroin and Prescription Drug Abuse,” statement before the Senate Caucus on International Narcotics Control, May 14, 2014, <https://www.drugabuse.gov/about-nida/legislative-activities/testimony-to-congress/2014/americas-addiction-to-opioids-heroin-prescription-drug-abuse>